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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,145	12/05/2001	Liora Cahalon	24214	4185

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EXAMINER	
HUI, SAN MING R	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,145	CAHALON ET AL.	
	Examiner	Art Unit	
	San-ming Hui	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12 July 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,5-13,16-19 and 21-36* is/are pending in the application.

4a) Of the above claim(s) *5,6,9,13,22,23,26 and 29* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1, 7-8, 10-12, 16-19, 21, 24-25, 27-28, 30-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7-21-06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and arguments July 12, 2006 have been entered. The outstanding rejection under 35 USC 112, first paragraph is withdrawn.

Upon reconsideration, the rejection under 35 USC 103(a) is restated below due to the claims encompass up to 20 monosaccharide units in the instant method.

Claims 5,6,9,13,22,23,26, and 29 are withdrawn form further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in response filed February 13, 2004.

Claims 1, 7-8, 10-12, 16-19, 21, 24-25, 27-28, 30-36 are examined to the extent they read on the elected species.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 7, 11, 12, 16-19, 27-28, 30-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Where applicant acts as his or her own lexicographer to specifically define a term of a claim contrary to its ordinary meaning, the written description must clearly redefine the claim term and set forth the uncommon definition so as to put one reasonably skilled in the art on notice that the applicant intended to so redefine that claim term. *Process*

Control Corp. v. HydReclaim Corp., 190 F.3d 1350, 1357, 52 USPQ2d 1029, 1033 (Fed. Cir. 1999). The term "oligosaccharide" in claims 1 and 7 is used by the claim to mean "up to 10 saccharide units, which each saccharid units comprise a disaccharide unit of formula (I)" [Examiner notes: up to 10 unit, and each unit is a disaccharides unit, in other words, the claims encompass up to 10 x 2 = 20 monosaccharides units], while the accepted meaning is "a carbohydrate that is made up of 2-10 monosaccharide units." (see Oligossacharide in Chemical Dictionary, 5th ed., McGraw-Hill, 1987). The term is indefinite because the specification does not clearly redefine the term.

Furthermore, the limitation "an oligosaccharide, where in said oligosaccharide consists of up to about 10 saccharide units and, within said units, comprises a disaccharide of formula (I)" recited in claim 1 renders the claims indefinite as to the oligosaccharide compounds employed in the instant method. It is not clear other than the disaccharide of formula (I), what exactly the compounds or structures would be encompassed by the claims. In essence, applicant attempts to claim the employment of oligosaccharide compound with only a part of the compound recited in the claim. It is not clear what other saccharide moieties can be attached to the compound. In other words, it recites "up to 10 saccharide units" without telling the one of ordinary skill in the art what these saccharide units are other than one of the saccharide units comprising dissacharide of formula (I).

Response to arguments

Applicant's arguments filed July 12, 2006 have been considered, but are not found persuasive. The instant specification discloses "up to 10 saccharide units". It does not disclose "up to 10 monosaccharide units". Since the arguments are directed to the description of "up to 10 monosaccharide units", the arguments are considered moot.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was

not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 7-8, 10-12, 16-19, 21, 24-25, 27-28, and 30-36 are rejected under 35 U.S.C. 103(a) as being unpatentable over '318 (US patent 4,882,318) in view of Vlodavsky et al. (Adv. Exp. Med. Biol., 992;13:317-327), references of record.

'318 teaches heparin and its related molecules for the treatment of tumor by inhibit heparanase activity and thereby decrease the metastasis of the tumor, especially lung cancer (See the abstract, col. 1 – 2). '318 teaches the dose of heparin and its related molecules useful for treating tumor metastasis as 50-500μg/kg/day (See claim 1).

'318 does not expressly teach the herein oligosaccharide compounds, with the herein claimed molecular weight or having up to 10 oligosaccharide units, for treating lung tumor metastasis.

Vlodavsky et al. teaches to optimize cancer therapy, one would want to chose a heparin compounds that has low potential for bFGF release but a high inhibition of heparanase activity (See page 317-320). Vlodavsky et al. teaches various factors would affect the heparanase inhibition activity and the bFGF release activity. Those factors are the size, sulfation, acetylation, the position where sulfation or desulfation of the heparin molecules (usually at the N- position) (See page 321-324, particularly, Fig. 1).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to employ the herein claimed heparin molecules, with the herein claimed molecular weight and herein claimed oligosaccharide units, for the treatment of lung cancer.

One of ordinary skill in the art would have been motivated to employ the herein claimed heparin molecules, with the herein claimed molecular weight, for the treatment of lung cancer. From the teachings of the cited prior art, modifying heparin oligosaccharide compounds with different sulfation at the N- position to the herein claimed heparin oligosaccharide compounds in order to maximized the heparanase inhibition, which is the mechanism to reduce tumor metastasis, would be reasonably expected to be useful in reducing tumor metastasis and thereby treating cancer. Furthermore, optimizing the number of saccharide units in the herein claimed heparin olecules would have been reasonably expected to be effective in minimize the undesirable effects and at the same time to maximize the therapeutic effect.

Response to arguments

Since the rejection under 35 USC 103(a) set forth in the previous office action mailed October 19, 2005 is restated, the response of Applicant's arguments filed January 19, 2006 is set forth below.

Applicant's argument filed January 19, 2006 averring the cited prior arts' failure to provide suggestion or motivation to adjust the length of the oligossacharides to less than 10 saccharide units have been considered, but are not found persuasive. Examiner

notes that applciant's arguments are directed to "oligosaccharides having up to 10 monosaccharide units", which is not claimed in the instant case. It is clear to one of ordinary skill in the art that the term "saccharide unit" encompasses monosaccharide, disaccharide and polysaccharide. Therefore, the instant claims encompass the use of saccharide compounds up to 20 monosaccharide units (see discussion above in the 35 USC 112, second paragraph).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to San-ming Hui whose telephone number is (571) 272-0626. The examiner can normally be reached on Mon 9:00 to 1:00, Tu - Fri from 9:00 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, PhD., can be reached on (571) 272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

San-ming Hui
Primary Examiner
Art Unit 1617